

IN THE UNITED STATES DISTRICT COURT
FOR THE MIDDLE DISTRICT OF NORTH CAROLINA

DUKE UNIVERSITY, a North)	
Carolina nonprofit and)	
educational institution,)	
OREXIGEN THERAPEUTICS, INC.,)	
a Delaware corporation,)	
)	
Plaintiffs,)	
)	
v.)	1:04CV532
)	
ELAN CORPORATION, PLC, an)	
Irish corporation,)	
ELAN PHARMACEUTICALS, INC.,)	
a Delaware corporation,)	
JULIANNE E. JENNINGS, an)	
individual,)	
EISAI CO., LTD., a Japanese)	
corporation,)	
ELAN PHARMA INTERNATIONAL LTD.,)	
)	
Defendants.)	

MEMORANDUM OPINION AND ORDER

OSTEEN, District Judge

Plaintiffs Duke University ("Duke") and Orexigen Therapeutics, Inc. ("Orexigen") bring this action against Defendants Elan Corporation, Elan Pharma International Ltd., Elan Pharmaceuticals, Inc., Eisai, Inc. ("Eisai"), Eisai Co., and Julianne E. Jennings. Plaintiffs seek a declaratory judgment of correct inventorship and ownership of a patent application and allege violations of the Copyright Act of 1976 ("Copyright Act"), as amended, 17 U.S.C. §§ 101 et seq., and of state common law. This matter is before the court on the following motions: (1) a

motion to dismiss under Federal Rule of Civil Procedure 12(b)(2) for lack of personal jurisdiction, made by Elan Corporation; (2) a motion to dismiss under Federal Rule of Civil Procedure 12(b)(6) for failure to state a claim, made by Elan Pharmaceuticals, Elan Corporation, and Ms. Jennings ("Elan defendants"); (3) a motion to strike under Federal Rule of Civil Procedure 12(f), made by the Elan defendants; (4) a motion to stay, made by the Elan defendants; and (5) a motion to dismiss under Federal Rules of Civil Procedure 12(b)(1) and 12(b)(6), made by Eisai.

I. BACKGROUND

Defendants Elan Corporation, Elan Pharma International Ltd., and Elan Pharmaceuticals, Inc. (the "Elan companies"), at times relevant to this action, owned the U.S. rights to the epilepsy drug zonisamide.¹ Two physicians employed by Duke, Dr. Kishore Gadde and Dr. Ranga Krishnan, developed an interest in conducting research on the use of zonisamide to treat obesity. In a meeting held in August 2000, Dr. Krishnan suggested to representatives of the Elan companies that zonisamide might be used to treat obesity, and in September and October 2000, Dr. Gadde submitted proposals to the Elan companies for the purpose of determining the Elan companies' interest in funding or providing samples of zonisamide for such a study. As a result, the Elan companies provided Duke with funding and zonisamide samples. The Elan

¹ Elan has since transferred these rights to Eisai.

companies and Duke did not enter into any agreement regarding restrictions on use of the funds and samples or rights to the results of the study.

The study was conducted at Duke Medical Center from March 2001 to March 2002. As the study progressed, Dr. Gadde provided updates to representatives of the Elan companies. On several occasions, representatives of the Elan companies requested and received written information about the study. The study ultimately indicated "that obese patients treated with zonisamide over a 16-week period experienced a significantly higher reduction in weight as compared to patients that did not receive the zonisamide." (Compl. ¶ 19.) In late 2001, at the request of a representative of the Elan companies, Dr. Gadde provided an explanation of possible pharmacological mechanisms by which zonisamide contributes to weight loss; additionally, Dr. Gadde provided the Elan companies with an abstract of a presentation he intended to make at a May 2002 meeting of the American Psychiatric Association.

In April 2002, at the initiation of Ms. Jennings, who was an employee of one of the Elan companies, Dr. Gadde participated in a telephone call with representatives of the Elan companies, including Ms. Jennings and J. Mark Hoch.² During the conversation, the representatives elicited from Dr. Gadde

² The representatives indicated that Hoch was from their regulatory department. Duke later learned that he was a patent attorney.

detailed information about the use of zonisamide to treat obesity.

Shortly after the day on which the conversation took place, Ms. Jennings filed a patent application with the U.S. Patent and Trademark Office ("PTO") involving the use of zonisamide to treat obesity. The application was filed without Duke's knowledge. Much of the important information in the application was provided to the Elan companies by Duke researchers. Portions of the application were copied directly from written materials provided by Duke researchers to the Elan companies. At least some of the information was provided by Dr. Gadde during the April telephone call. In May 2002, Duke filed its own patent application involving the use of zonisamide to treat obesity.³

II. ANALYSIS

Duke's claims, including the declaratory judgment, copyright violation, and various state law claims, revolve around its belief that Elan has wrongfully claimed ownership of Duke's invention. Both the Elan defendants and Eisai have requested that the court dismiss Duke's declaratory judgment claims, arguing that those claims are committed to the PTO, and both seek dismissal of Duke's state law claims on various grounds. Additionally, the Elan defendants have filed a motion requesting that the court strike a portion of the complaint⁴ and a motion to

³ Duke has since licensed this application to Orexigen.

⁴ The Elan defendants have moved to strike Duke's request
(continued...)

stay all claims remaining after consideration of their motion to dismiss. Finally, Elan Corporation has filed a motion to dismiss claiming lack of personal jurisdiction.

For reasons stated below, the court concludes that Duke's declaratory judgment claims should be dismissed and its remaining claims stayed pending a decision on the two patent applications by the PTO. Because of this, the court will not rule at this time on the motions as they pertain to the remaining claims but will defer a ruling until the stay is lifted. The court will begin by addressing Elan Corporation's arguments regarding lack of personal jurisdiction, will continue by explaining the decision regarding the declaratory judgment claim, and will conclude by explaining the decision to stay the proceedings.

A. Claims Against Elan Corporation

Elan Corporation has asked the court to dismiss the claims against it under Rule 12(b)(2) due to lack of personal jurisdiction. When a defendant makes a 12(b) motion to dismiss for lack of personal jurisdiction, the plaintiff bears the burden of proving the existence of jurisdiction over the defendant by a preponderance of the evidence. Combs v. Bakker, 886 F.2d 673, 676 (4th Cir. 1989). "But when, as here, the court addresses the question on the basis only of motion papers, supporting legal memoranda and the relevant allegations of a complaint, the burden

⁴(...continued)
for statutory damages and attorney's fees under the Copyright Act. This motion is not opposed by Duke and will be granted without further comment.

on the plaintiff is simply to make a prima facie showing of a sufficient jurisdictional basis in order to survive the jurisdictional challenge." Id. The district court "must construe all relevant pleading allegations in the light most favorable to the plaintiff, assume credibility, and draw the most favorable inferences for the existence of jurisdiction." Id.

Elan Corporation suggests that the only basis for personal jurisdiction over it is its status as a "great-grandparent" corporation of Elan Pharmaceuticals, and it argues that this status is insufficient to support jurisdiction. Even if Elan Corporation's relationship with Elan Pharmaceuticals may not, by itself, support jurisdiction, the issue is not resolved. Duke's claim is not based solely on the corporate relationship; rather, Duke has alleged that Elan Corporation's agents directly interacted with Dr. Gadde. Although it may be unlikely that those allegations are true, the court must accept them as true for the purposes of this motion. Elan Corporation has not argued that these contacts were insufficient to establish personal jurisdiction. Based upon the pleadings, the court concludes that Duke has made a prima facie showing of personal jurisdiction over Elan Corporation. Nonetheless, Elan Corporation is free to raise the issue again through another type of motion, and the court affirms that the "plaintiff must eventually prove the existence of personal jurisdiction by a preponderance of the evidence, either at trial or at a pretrial evidentiary hearing." New

Wellington Fin. Corp. v. Flagship Resort Dev. Corp., 416 F.3d 290, 294 n.5 (4th Cir. 2005) (internal quotation marks omitted).

B. Declaratory Judgment Act Claims

In its First Claim for Relief, Duke seeks "a declaratory judgment of correct inventorship under 28 U.S.C. § 2201 and 35 U.S.C. § 116, and for a declaration of proper assignment under 28 U.S.C. § 2201 and 35 U.S.C. § 261." (Compl. ¶ 41.) Both the Elan defendants and Eisai have filed motions seeking the dismissal of this claim under Rule 12(b)(6).⁵ A defendant's motion to dismiss under Rule 12(b)(6) tests the legal sufficiency of pleadings, but does not seek to resolve disputes surrounding the facts. Republican Party of N.C. v. Martin, 980 F.2d 943, 952 (4th Cir. 1992). A court must determine only if the challenged pleading fails to state a claim upon which relief can be granted. Fed. R. Civ. P. 12(b)(6). A pleading "should not be dismissed for failure to state a claim unless it appears beyond doubt that the plaintiff can prove no set of facts in support of his claim which would entitle him to relief." Conley v. Gibson, 355 U.S. 41, 45-46, 78 S. Ct. 99, 102 (1957). The pleading must be "liberally construed" in the light most favorable to the non-moving party and allegations made therein are taken as true. Jenkins v. McKeithen, 395 U.S. 411, 421, 89 S. Ct. 1843, 1849 (1969).

⁵ Both motions adopt essentially the same reasoning. Because the Elan defendants' motion was filed first, the court will address it specifically in this discussion and will not refer to Eisai's brief.

The Elan defendants' argument is grounded on the theory that the power to correct inventorship on patent applications is vested by 35 U.S.C. § 116⁶ solely in the PTO and, therefore, a federal district court may not hear a case that requires it to determine whether a party is properly named as an inventor on an application. A review of the decisions by courts of other districts on this topic reveals disagreement regarding whether these actions should be heard. Compare Post Performance, LLC v. Renaissance Imports, Inc., 333 F. Supp. 2d 834 (E.D. Mo. 2004) (allowing a similar claim to proceed), and Heineken Technical Servs., B.V. v. Darby, 103 F. Supp. 2d 476 (D. Mass. 2000) (same), with Sagoma Plastics, Inc. v. Gelardi, 366 F. Supp. 2d 185 (D. Me. 2005) (dismissing a similar claim), and Display Research Labs., Inc. v. Telegen Corp., 133 F. Supp. 2d 1170 (N.D. Cal. 2001) (same). The Elan defendants argue that the court does not have jurisdiction over Duke's claims; framing the argument in this way is consistent with the language used in the case law. See, e.g., Display Research Labs., 133 F. Supp. 2d at 1174 ("This Court therefore finds that it does not have jurisdiction to correct a patent application"). Nonetheless, the cases suggest that Elan's motion raises two separate but related

⁶ In relevant part, section 116 states:

Whenever through error a person is named in an application for patent as the inventor, or through error an inventor is not named in an application, and such error arose without any deceptive intention on his part, the Director may permit the application to be amended accordingly, under such terms as he prescribes.

questions: (1) whether the court has subject matter jurisdiction over the claim, and (2) whether Duke has a cause of action. The court will address both of these questions.

Federal court jurisdiction over claims involving patent law is created by 28 U.S.C. § 1338.⁷ Jurisdiction exists under § 1338 if "a well-pleaded complaint establishes either that federal patent law creates the cause of action or that the plaintiff's right to relief necessarily depends on resolution of a substantial question of federal patent law, in that patent law is a necessary element of one of the well-pleaded claims."

Christianson v. Colt Indus. Operating Corp., 486 U.S. 800, 809, 108 S. Ct. 2166, 2174 (1988). Several district courts have concluded claims for correction of inventorship on a patent application satisfy the jurisdictional requirements. See Concrete Washout Sys. v. Minegar Envtl. Sys., Inc., No. CIVS041005WBSDAD, 2005 WL 1683930, at *3 (E.D. Cal. July 12, 2005) ("Several district courts, whose reasoning the court finds persuasive, have determined that federal courts have subject matter jurisdiction to resolve inventorship issues under 28 U.S.C. § 1338(a)."); Post Performance, 333 F. Supp. 2d at 840 ("[T]he court concludes that there is an inventorship issue providing a substantial enough issue for federal jurisdiction."); Heineken, 103 F. Supp. 2d at 477-79 (finding jurisdiction under

⁷ "The district courts shall have original jurisdiction of any civil action arising under any Act of Congress relating to patents" 28 U.S.C. § 1338(a).

§ 1338 over a similar claim). The court agrees with the conclusion reached in these cases.

This conclusion does not decide the issue, however, because the court's jurisdiction is meaningless if Duke has no cause of action. Section 116 does not include a private cause of action for the correction of inventorship on patent applications.⁸

Display Research Labs, 133 F. Supp. 2d at 1173; see also Eli Lilly & Co. v. Aradigm Corp., 376 F.3d 1352, 1356 n.1 (Fed. Cir. 2004) (stating in dicta that "[t]he text of section 116 . . . plainly does not create a cause of action in the district courts to modify inventorship on pending patent applications.").

Similarly, the statutory provision on which Duke relies for its claim of assignment, 35 U.S.C. § 261,⁹ creates no cause of action for the correct assignment of applications. The section allows

⁸ The rationale behind such a conclusion is that 35 U.S.C. § 116 mentions only correction of inventorship by the Commissioner of Patents, not federal courts. See Display, 133 F. Supp. 2d at 1173. A comparison of section 116 with its companion statute, 35 U.S.C. § 256, which deals with the correction of inventorship on issued patents and does create a private right of action in federal court, suggests that the statutory scheme contemplates federal court involvement only after a patent has issued. E.I. Du Pont de Nemours & Co. v. Okuley, 344 F.3d 578, 584 (6th Cir. 2003); Sagoma Plastics, 366 F. Supp. 2d at 187-88.

⁹ In relevant part, section 261 states:

Applications for patent, patents, or any interest therein, shall be assignable in law by an instrument in writing. The applicant, patentee, or his assigns or legal representatives may in like manner grant and convey an exclusive right under his application for patent, or patents, to the whole or any specified part of the United States.

applications to be assigned by the applicants, but it makes no mention of federal court involvement or circumstances under which applications must be assigned. Thus, there is no direct cause of action for either of Duke's claims.

Nonetheless, Duke has not brought its claims directly under § 116 and § 261, but under the Declaratory Judgment Act (the "Act"), 28 U.S.C. § 2201. The Declaratory Judgment Act states that "[i]n a case of actual controversy within its jurisdiction . . . any court of the United States . . . may declare the rights and other legal relations of any interested party seeking such declaration, whether or not further relief is or could be sought." "The purpose of the Act is to enable a person who is reasonably at legal risk because of an unresolved dispute, to obtain judicial resolution of that dispute without having to await the commencement of legal action by the other side." BP Chems. Ltd. v. Union Carbide Corp., 4 F.3d 975, 977 (Fed. Cir. 1993).

The Act applies only to cases of actual controversy. To determine whether such a controversy exists, a court must determine "whether the facts alleged, under all the circumstances, show that there is a substantial controversy, between parties having adverse legal interests, of sufficient immediacy and reality to warrant the issuance of a declaratory judgment." Maryland Cas. Co. v. Pacific Coal & Oil Co., 312 U.S. 270, 273, 61 S. Ct. 510, 512 (1941). There is no particularized test for determination of the existence of an actual controversy

in patent application cases. However, in patent infringement cases, the Federal Circuit has created a two-part test to determine whether an actual controversy exists: "There must be both (1) an explicit threat or other action by the patentee, which creates a reasonable apprehension on the part of the declaratory plaintiff that it will face an infringement suit, and (2) present activity which could constitute infringement or concrete steps taken with the intent to conduct such activity." BP Chems. Ltd., 4 F.3d at 978. Although this test does not apply directly to the case at hand, it does provide useful guidance.

The test suggests that the controversy requirement is only satisfied by the prospect of one of the parties being able to bring the dispute to court. In the context of a patent infringement suit, a disagreement between two parties over the extent of one party's patent rights is insufficient to support a declaratory judgment action, even when the dispute can only be settled by the application of patent law; rather, there must be a prospect of legal action by one of the parties. Applying the reasoning to this case, there is no controversy of sufficient immediacy to support a declaratory judgment action. Although Duke and Elan have adverse interests, in the sense that they both lay claim to the same invention, neither party has a right that can be enforced. Just as Duke may not sue Elan directly, Elan has no cause of action to sue Duke under that provision. The court is not aware that Elan has ever threatened to sue Duke. Furthermore, both applications are currently under consideration

by the PTO, and Duke has petitioned the PTO for an interference. The court concludes that, although the controversy between the parties is real, it has not reached the stage where a federal court should be involved. Rather, it is currently in the process of being resolved through established channels and lacks the immediacy to be considered an actual controversy under the Declaratory Judgment Act. Thus, Duke has no cause of action under the Act.

Even were there an actual controversy, the court would refrain to exercise jurisdiction over this action. "[A] district court is not required to exercise declaratory judgment jurisdiction, but has substantial discretion to decline that jurisdiction." Teva Pharm. USA, Inc. v. Pfizer, Inc., 395 F.3d 1324, 1331 (Fed. Cir. 2005). The court is persuaded that the PTO is a better forum for resolving inventorship disputes because of its expertise in the area and its superior access to the relevant information. Additionally, in light of the intent of Congress to reserve these questions for the PTO, the court believes that it would be inappropriate to allow Duke to bypass the established administrative procedure through a declaratory judgment action. Cf. Consolidated World Housewares, Inc. v. Finkle, 831 F.2d 261, 265 (Fed. Cir. 1987) ("[A district court does] not have original jurisdiction to conduct an interference under § 1338(a) or under any other statute because the United States Patent and Trademark Office was granted that function exclusively").

C. All Other Claims

The Elan defendants have asked the court to stay all the claims that have not been dismissed until the PTO has made a determination of inventorship. Because the remaining claims depend on the resolution to the question of inventorship, it is appropriate for the court to stay further proceedings and to refrain from consideration of the motion to dismiss as it pertains to these claims. The court's power to stay proceedings is "incidental to the power inherent in every court to control the disposition of the causes on its docket with economy of time and effort for itself, for counsel, and for litigants." Landis v. North Am. Co., 299 U.S. 248, 254, 57 S. Ct. 163, 166 (1936). In determining whether to exercise this power, a court "must weigh competing interests and maintain an even balance." Id. at 254-55, 57 S. Ct. at 166. If there is a possibility that the stay could be detrimental to another party, then the movant must justify it by "clear and convincing circumstances outweighing" such possible harm. Williford v. Armstrong World Indus., Inc., 715 F.2d 124, 127 (4th Cir. 1983).

Weighing in favor of a stay is the importance of the PTO's determination to Duke's claims. At this time, it is not clear whether this matter involves the theft of an invention or the misappropriation of information. The resolution of this question is clearly important to Duke's arguments on the merits of three of the four state law claims. With regard to Elan's assertion that Duke's claim of conversion is preempted by federal copyright law, Duke states that "it is Elan's filing of a patent

application for Duke's invention and wrongful assertion of ownership of that invention and patent application that form the basis of Duke's conversion claim." (Pl.'s Mem. Law Opp'n Elan Corporation, Elan Pharmaceuticals, Inc., and Julianne E. Jennings' Mot. Dismiss at 7.) The same argument is used to explain why Duke's unfair and deceptive trade practices claim is not preempted. Similarly, with regard to its claim of unjust enrichment, Duke indicated the following: "Elan unjustly enriched itself by filing a patent application on Duke's invention, falsely claiming ownership of Duke's invention. The mere receipt of . . . information by Elan does not form the basis of Duke's claim." (Id. at 8 (citation omitted).) Additionally, for all of its remaining claims, Duke seeks actual damages. Duke's actual damages are highly dependent on whether its injury is the theft of an invention or a misappropriation of information. It is possible that the PTO may ultimately determine that the invention is not patentable by anyone, in which case the scope of Duke's damages would be limited.

Weighing against a stay is the fact that its length is unpredictable. The PTO has not yet declared an intervention, and there is no way of knowing when or if the PTO will do so. Duke argues that Orexigen would be prejudiced by a lengthy stay because it is currently seeking investors and resolution of this matter would make Orexigen more attractive. This argument is weakened by the court's decision that it will not hear claims of correct inventorship and ownership; a decision in favor of Duke

on the copyright and state law claims would not resolve questions of inventorship and ownership in Orexigen's favor. There is no other particular prejudice to Duke from a long stay, except that Duke will have to wait to be compensated for any wrong it may have suffered.

On balance, the court concludes that it is appropriate to stay these proceedings to resolve the uncertainties surrounding Duke's claims. For that reason, the court will not at this time evaluate the motions to dismiss by either the Elan defendants or Eisai as they pertain to Duke's additional claims. Those motions will be considered when the stay is lifted.

III. CONCLUSION

For the reasons stated herein,

IT IS ORDERED that Elan Corporation's Motion to Dismiss for Lack of Personal Jurisdiction [16] is DENIED.

IT IS FURTHER ORDERED that the Motion to Dismiss for Failure to State a Claim [18] filed by Elan Corporation, Elan Pharmaceuticals, Inc., and Julianne E. Jennings is GRANTED as to Duke's First Claim for Relief.

IT IS FURTHER ORDERED that the Motion to Strike [19] filed by Elan Corporation, Elan Pharmaceuticals, Inc., and Julianne E. Jennings is GRANTED.

IT IS FURTHER ORDERED that the Motion to Stay [17] filed by Elan Corporation, Elan Pharmaceuticals, Inc., and Julianne E. Jennings is GRANTED as to the remaining claims for relief.

IT IS FURTHER ORDERED that the Motion to Dismiss [26] filed by Eisai, Inc. is GRANTED as to Duke's First Claim for Relief.

This the 30th day of January 2006.


United States District Judge